On page 2, line 14 after "DSM" please insert --(Deutsche Sammlung von Mikroorganismen und Zellkulturen GmbH (German-type collection of microorganisms), Mascheroder Weg 1b, D-38124, Braunschweig, Germany)--.

IN THE CLAIMS:

Please amend the claims as follows:

2. (Twice amended) The antibody of [claim] Claim 1, wherein said antibody is a polyclonal antibody.

3. (Twice amended) The antibody of [claim] Claim 1, wherein said antibody is a monoclonal antibody.

4. (Twice amended) The antibody of [claim] Claim 3, wherein said antibody is deposited under ACC 2207 with [DSM (German-type culture collection for microorganisms)] the Deutsche Sammlung von Mikroorganismen und Zellkulturen GmbH (DSM).

REMARKS

Claims 1-4 are pending in this application. The claims as pending are attached hereto as *Appendix A*.

I. THE AMENDMENTS TO THE SPECIFICATION AND THE CLAIMS

The Specification has been amended for clarity by listing the complete address of the Deutsche Sammlung von Mikroorganismen und Zellkulturen GmbH (the German-type collection of microrganisms). The claims have been amended to include the full name of the depository, and to correct typographical inconsistencies. No new matter is added by these amendments. Accordingly, entry thereof under 37 C.F.R. § 1.111 is respectfully requested.

II. REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH

Claim 4 is rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter that was not described in the Specification in such a way as to enable one skilled in the art to which it pertains to make or use the invention.

Claim 4 recites a monoclonal antibody "deposited under ACC 2207 with DSM (German-type culture collection for microorganisms)." The Examiner asserts that the reproduction of antibodies is an unpredictable event, and thus that the antibody must be made available to the public as part of a recognized public depository. Applicants point out that they deposited a sample of a hybridoma cell line that produces the antibody of Claim 4 with the DSM on February 15, 1995. Deposits to the DSM are governed by the terms of the Budapest Treaty. Applicants will submit the Declaration by an appropriate person confirming this deposit as soon as such Declaration has been executed. Attached hereto is a copy of the deposit receipt (in the original German). Further, the Specification has been amended to recite the address of the DSM.

In view of the above, the rejection under § 112, first paragraph, is moot. Applicants respectfully request that it be withdrawn.

III. REJECTION UNDER 35 U.S.C. § 102 (b)

Claims 1 and 2 are rejected under 35 U.S.C. § 102(b) as being anticipated by a public use or sale of the invention more than one year prior to the filing date of the present application. Applicants respectfully traverse.

35 U.S.C. § 102(b) states in relevant part that a person shall be entitled to a patent unless "the invention was . . . described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States."

The Examiner asserts that Janssen *et al.*, 1995, *Journal of Biological Chemistry* 270:11222-11229 (hereinafter "Janssen") teaches an antibody identical to one recited by Claims 1 and 2, and that Janssen bought the antibody from Cappel, Organon Teknika N.V. (hereinafter "Cappel"). The Examiner calculates that the date of the sale could be no later than February 20, 1995, and concludes that this sale anticipates Claims 1 and 2 under § 102(b).

Even assuming, *arguendo*, that Claims 1 and 2 recite the Cappel antibody, the Examiner has not met his burden of proving that Claims 1 and 2 are anticipated by Janssen. The relevant passage from Janssen says that "[t]he anti-histidine tag antiserum was *obtained* from Cappel." Obtained does not necessarily mean bought. For example, Cappel might have

donated the antibody to Janssen for the purpose of testing it before offering it for sale to the public. Experimental use is not invalidating use under § 102(b) (*see, e.g.,* Continental Can Co. v. Monsanto Co., 20 U.S.P.Q.2d 1746, 1750 (C.A.F.C. 1991) ("[T]he 'on sale' bar of § 102(b) does not arise simple because the intended customer was participating in development and testing.")). This possibility is supported by the (undated) Cappel advertisement (*see* Office Action, reference V), which cites Janssen as a reference that proves the efficacy of the Cappel antibody.

Even if one further assumed, *arguendo,* that Cappel sold the antibody to Janssen, the sale did not occur in the United States, as is required by § 102(b) (*see* M.P.E.P. § 706.02(c) ("The language 'in this country' means in the United States only and does not include other WTO or NAFTA member countries."). The alleged Buyers, the authors of Janssen, resided in The Netherlands (*see,* Janssen at page 11222, authors' line). The alleged Seller, Cappel, resided in Belgium (*see,* Janssen at page 11223, second column, third paragraph).

In view of the above, the Examiner has not met his burden of proving that Janssen anticipates Claims 1 and 2 under the on sale bar of § 102(b). Applicants respectfully request that this rejection be withdrawn.

IV. REJECTION UNDER 35 U.S.C. § 103 (a)

Claims 1-3 are rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Janssen in view of Sevier *et al.*, 1981, *Clinical Chemistry* 27:1797-1806 (hereinafter "Sevier"). Applicants respectfully traverse.

In order for a reference to be available as prior art, such reference must be published before the priority date of the claimed invention. The primary reference, *i.e.,* Janssen, relied on by the Examiner in making an obviousness rejection, was published in May 1995. *See,* Janssen, page 11222, header. However, Applicants are entitled to rely on the filing date of their original German application as their priority date (*see* 35 U.S.C. §§ 104 and 119), which was filed on March 1, 1995. Applicants will submit certified copies of the original German application from which the instant Application derives and the official English translation thereof.

B

In light of the foregoing, Janssen is not available as § 103 prior art against the instant Application. Therefore, Applicants respectfully request that this rejection under 35 U.S.C. § 103(a) be withdrawn.

CONCLUSION

In view of the above amendments and remarks, the subject application is believed to be in good and proper order for allowance. Early notification to this effect is earnestly solicited.

If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subjection application, the Examiner is encouraged to call the undersigned at (650) 493-4935. The Applicants also invite a personal interview with the Examiner, if the Examiner does not find the response persuasive and intends to maintain the rejections of record. It is believed that such an interview could respond to any further questions that the Examiner might have in connection with the subject application.

If any fee is required in connection with filing of this response, the Commissioner is authorized to charge Pennie & Edmonds LLP Deposit Account No. 16-1150 for the appropriate amount.

A copy of this sheet is attached.

Respectfully submitted,

Date February 11, 2000

43,341
Birgit Millauer (Reg. No.)

for Laura A. Coruzzi (Reg. No.) 30,742
PENNIE & EDMONDS LLP
1155 Avenue of the Americas
New York, New York 10036-2711
(212) 790-9090

Enclosures

APPENDIX A

1. An antibody against a fusion polypeptide comprising a histidine portion, wherein said antibody is directed against said histidine portion, and wherein said histidine portion comprises 6-18 histidine residues.

2. The antibody of Claim 1, wherein said antibody is a polyclonal antibody.

3. The antibody of Claim 1, wherein said antibody is a monoclonal antibody.

4. The antibody of Claim 3, wherein said antibody is deposited under ACC 2207 with the Deutsche Sammlung von Mikroorganismen und Zellkulturen GmbH (DSM).